In the claims

The following amendments are made with respect to the claims in the International application PCT/GB2003/005049.

This listing of claims will replace all prior versions and listings of claims in this application.

Claims

1 (Original). A composition for treating or preventing an inflammatory or hyperproliferative mucocutaneous disorder, comprising a protease inhibitor and a gelling agent.

2 (Currently amended). The composition ~~of Claim~~ according to claim 1, wherein the protease inhibitor is an alpha 1-antitrypsin.

3 (Currently amended). The composition [[of]] according to claim 2, wherein the alpha 1-antitrypsin is a natural, synthetic or recombinant alpha 1-antitrypsin.

4 (Currently amended). The composition ~~of any preceding~~ according to claim 1, wherein the protease inhibitor is a modified peptide, biologically active fragment, substantially homologous polypeptide, oligopeptide, homodimer, heterodimer, variant, derivative, and/or an analog of alpha 1-antitrypsin.

5 (Currently amended). The composition ~~of any preceding~~ according to claim 1, further comprising a physiological buffer at a pH from about 6 to about 9.

6 (Currently amended). The composition [[of]] according to claim 5, wherein the buffer has a pH of from about 6.5 to about 7.5.

7 (Currently amended). The composition according to ~~of any preceding~~ claim 1, wherein the gelling agent is hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid, a polyoxyethylene-polyoxypropylene block copolymer, or a combination thereof.

8 (Currently amended). The composition according to ~~of any preceding~~ claim 1, further comprising one or more pharmaceutically active agents.

9 (Currently amended). The composition ~~of any preceding~~ according to claim 1, which is sterile.

10 (Currently amended). A pharmaceutical composition formulated ~~Use of a protease inhibitor for the manufacture of a gel composition,~~ for use in preventing or treating an inflammatory or hyperproliferative mucocutaneous disorder wherein said composition comprises a protease inhibitor and a gelling agent, and a pharmaceutical carrier.

11 (Currently amended). The composition ~~use of~~ according to claim 10, wherein the inhibitor is ~~as defined in any of claims 2 to 4~~ alpha 1-antitrypsin.

12 (Currently amended). The composition ~~use of~~ according to claim 10 ~~or claim 11~~, wherein the composition further comprises one or more of the following:
a physiological buffer at a pH from about 6 to about 9;
a gelling agent that is hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid, a polyoxyethylene-polyoxypropylene block copolymer, or a combination thereof; and/or
one or more pharmaceutically active agents ~~a component as defined in any of claims 5 to 8~~.

13 (Cancelled).

14 (Cancelled).

15 (Cancelled).

16 (Original). A method of making a protease inhibitor gel composition, comprising:

(a) mixing a powdered gelling agent with an aqueous solution to form a gel;
(b) adjusting the pH of the gel to a pH of from about 5.5 to about 9.0;
(c) sterilizing the gel; and
(d) combining a protease inhibitor with the gel to form the protease inhibitor gel.

17 (Currently amended). The method ~~of~~ according to claim 16, wherein the aqueous solution is a physiological buffer.

18 (Currently amended). The method ~~of~~ according to claim 16 ~~or 17~~, further comprising adjusting the pH of the protease inhibitor gel from about 5.5 to about 9.0.

19 (Currently amended). The method ~~of any of~~ according to claim[[s]] 16 ~~to 18~~, wherein the protease inhibitor is an alpha 1-antitrypsin.

20 (Currently amended). The method ~~of any of~~ according to claim[[s]] 16 ~~to 19~~, wherein the gelling agent is hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid, polyoxyethylene-polyoxypropylene block copolymer, or a combination thereof.

21 (Currently amended). The method ~~of any of~~ according to claim[[s]] 16 ~~to 20~~, wherein the sterilizing comprises irradiation.

22 (Currently amended). The method ~~of any of~~ according to claim[[s]] 16 ~~to 21~~, further comprising lyophilizing the protease inhibitor gel.

23 (Currently amended). A method ~~of preventing or treating~~ for the treatment or prevention of an inflammatory or hyperproliferative mucocutaneous disorder, wherein said method ~~comprising~~ comprises administering to a subject in need thereof an effective amount of a composition comprising a protease inhibitor and a gelling agent.

24 (Currently amended). The method [[of]] according to claim 23, wherein the protease inhibitor is an alpha-1 antitrypsin.

25 (Currently amended). The method [[of]] according to claim 23, wherein the composition further comprises a physiological buffer at a pH from about 6 to about 9.

26 (Currently amended). The method [[of]] according to claim 25, wherein the buffer has a pH of from about 6.5 to about 7.5.

27 (Currently amended). The method [[of]] according to claim 23, wherein the gelling agent is hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid, polyoxyethylene-polyoxypropylene block copolymer, or a combination thereof.

28 (Currently amended). The method [[of]] according to claim 24, wherein the alpha 1-antitrypsin is a natural, synthetic or recombinant alpha 1-antitrypsin.

29 (Currently amended). The method [[of]] according to claim 23, wherein the composition further comprises one or more pharmaceutically active agents.

30 (Currently amended). The method [[of]] according to claim 23, wherein the disorder is a dermatological disorder, disorder of the ear, ocular disorder, disorder of the gastrointestinal tract, or disorder of the urinary tract.

31 (Currently amended). The method [[of]] according to claim 23, wherein the disorder is a dermatological disorder selected from the group consisting of atopic dermatitis; skin photodamage; extrinsic skin aging; skin irritation; chronic, burn and ulcer wounds; acne; psoriasis; lichen (particularly lichen planus); basal or squamous cell carcinoma (Bowen's disease); Kaposi's sarcoma; keratosis, such as actinic or seborrheic keratosis; and disorders of keratinization, such as ichthyosis (particularly lamellar ichthyosis) and keratoderma.

32 (Currently amended). The method [[of]] according to claim 23, wherein the disorder is otitis, conjunctivitis, colitis or intestinal cystitis.

33 (Currently amended). The method [[of]] according to claim 23, wherein the subject is a mammal.